

Dockets Management Branch  
The Food and Drug Administration  
Department of Health & Human Services, Rm. 1-23  
12420 Parklawn Dr.  
Rockville, MD 20857

Date: 6/13/00

Re: <sup>DUCKET NUMBER</sup> 99P-1340/CP 1 — Petition to Have *Eternity* eau de parfum declared "Misbranded"

JUN 19 10:20

Dear Sir or Madam:

In May 1999, the Environmental Health Network (EHN) submitted the above petition to have Calvin Klein's *Eternity* eau de parfum declared "misbranded." I am writing because I fully support this petition and request that the FDA give it careful attention with regard to your regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10. Regulation 21CFR Sec. 740.10 states:

Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

"Warning — The safety of this product has not been determined."

As the petition shows, *Eternity* contains toxic ingredients and ingredients whose safety have not been substantiated. There is no warning label on its packaging.

We all have a right to know the status of safety testing of the ingredients in products such as *Eternity* so that we can protect ourselves and our families from toxic chemicals that may cause health problems. Most people are not aware that most fragrance materials have only limited safety testing. They wrongfully assume these products are safe to use in any setting and are surprised when people complain.

Like tobacco smoke, the harmful chemicals currently used in these products may affect the health of many people, including: people with asthma, chemical sensitivities, chronic fatigue, and other environmental illnesses. Children are particularly vulnerable to toxic chemicals found in products purchased and used by their parents, caregivers and teachers. When I am exposed to fragrance products I can experience any of the following symptoms based upon the chemical fragrance product I encounter:

- |  |   |   |   |
|--|---|---|---|
| <input checked="" type="checkbox"/> anaphylaxis/shock  | <input type="checkbox"/> double vision                      | <input type="checkbox"/> incoherence                  | <input checked="" type="checkbox"/> nausea            |
| <input checked="" type="checkbox"/> anxiety, restlessness  | <input checked="" type="checkbox"/> ear pain                | <input type="checkbox"/> incontinence                 | <input type="checkbox"/> nose bleeds                  |
| <input type="checkbox"/> asthma  | <input checked="" type="checkbox"/> eczema                  | <input checked="" type="checkbox"/> irritability      | <input checked="" type="checkbox"/> rashes            |
| <input checked="" type="checkbox"/> breathing difficulty   | <input type="checkbox"/> eyes, watery or dry                | <input type="checkbox"/> joint aches                  | <input type="checkbox"/> seizures                     |
| <input type="checkbox"/> bronchitis  | <input type="checkbox"/> fatigue                            | <input type="checkbox"/> laryngitis                   | <input type="checkbox"/> short-term mem. loss         |
| <input checked="" type="checkbox"/> can't concentrate  | <input checked="" type="checkbox"/> flushing                | <input type="checkbox"/> lethargy                     | <input type="checkbox"/> sinusitis                    |
| <input checked="" type="checkbox"/> coughing   | <input checked="" type="checkbox"/> headaches               | <input checked="" type="checkbox"/> lymph nodes swell | <input type="checkbox"/> sneezing                     |
| <input type="checkbox"/> depression  | <input checked="" type="checkbox"/> heart beat irregularity | <input checked="" type="checkbox"/> mood swings       | <input checked="" type="checkbox"/> sores, skin/mouth |
| <input type="checkbox"/> disorientation  | <input checked="" type="checkbox"/> hives                   | <input type="checkbox"/> muscle pain/weakness         | <input type="checkbox"/> swallowing difficulty        |
| <input type="checkbox"/> dizziness   | <input type="checkbox"/> hypertension                       | <input checked="" type="checkbox"/> nasal congestion  | <input type="checkbox"/> tinnitus                     |
| <input checked="" type="checkbox"/> other: <u>Quercetin + multiple chemical sensitivity syndrome</u> |   |   |   |

Please act on behalf of the millions of people who have suffered physical illness and injury resulting from fragrance exposure at work, at school and in social settings. These toxic chemicals act as powerful barriers to people disabled by asthma and chemical sensitivities. Toxic chemicals in fragrances have already ruined countless lives. Thank you.

Sincerely,

Alise Farver  
your name

32 Alise Way, Huntington Sta. NY 11746  
address, city/st/zip

Newsletters and everyone who feels people have a right to know, please copy, share, tell your friends and WRITE the FDA ... today!

99P-1340

C637

## **\* PERFUME \***

### **A FEW THINGS YOU SHOULD KNOW**

Today's perfume is not made from flowers but from toxic chemicals. More than 4,000 chemicals are used in fragrances. Of these, 95% are made from petroleum. That's about as romantic as toxic waste. No agency regulates the fragrance industry, yet perfume chemicals are as damaging to your health as tobacco smoke.

Here is a list of some chemicals found in fragrances: toluene, formaldehyde ethanol, benzene derivatives, acetone, limonene, ethylene, methylene chloride, and many others known to cause cancer, birth defects, infertility, nervous system damage, and other injuries.

Toluene was found in every fragrance sample collected by the U.S. Environmental Protection Agency for a 1991 report. "Toluene was most abundant in the auto parts store as well as the fragrance section of the department store." Toluene has been proven to cause cancer and nervous system damage and is designated as "Hazardous Waste."

There has been a dramatic increase in the amount of people who are made sick by fragrances. Because so many products are now scented, people are constantly exposed. Babies and children are most vulnerable. Exposure can cause many symptoms and chronic illness. Here is a list of some: dizziness, headaches, asthma attacks, heart palpitations, seizures, swollen lymph glands, muscle aches and spasms, stomach cramps, nausea, vomiting, rashes, "hay fever" symptoms, difficulty concentrating, neuromotor dysfunction, loss of consciousness, and a disease called Multiple Chemical Sensitivities.

Even if you're healthy and don't feel the effects yet, your health is still being damaged. You're gambling on how long you have before your body can no longer cope with toluene and other poisons.

Save your money and your health by not using unnecessary scented products.

FOR MORE INFORMATION-  
CALL ALICE FARBER  
516-271-4109

## Multiple Chemical Sensitivity

### WHAT IS M.C.S.?

The U.S. Department of Health and Human Services defines it as an acquired chronic syndrome. It is described as a severe toxic, allergic-like reaction to extremely low levels of chemicals in our environment, that are generally accepted to be safe.

MCS has developed over the past four decades and is caused by overexposure to some 100,000 new, more toxic synthetic chemicals.

Research contends that a victim's body becomes unable to cleanse its tissues of chemicals to which it is exposed, either in small doses over time or from a single tremendous dose. Exposure can come from the air, food, water or skin contact. These chemical irritants come from a great variety of sources. These include, but are not limited to plastics, cleaning products, pesticide, solvents, inks, tobacco smoke, fuels, natural gas, auto exhaust, scented products, synthetic fabrics, leather, glues, building materials, carpeting, pharmaceuticals and numerous other organic and inorganic compounds. As the body breaks down, an ever increasing number of chemicals, including some unrelated to the initial exposure, are found to trigger a reaction. Hence the name: Multiple Chemical Sensitivity.

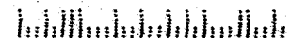
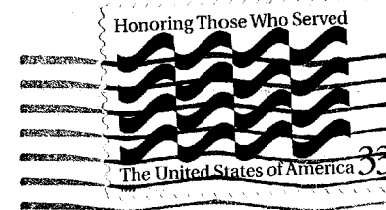
MCS affects multiple organ systems, especially the central nervous, immune, respiratory, musculoskeletal, endocrine, and digestive systems. Symptoms vary in severity and duration, and may include headaches, dizziness, nausea, fatigue, exhaustion, respiratory problems, aching joints and muscles, memory and concentration problems, irritated eyes, nose, ears, throat, skin, odor intolerance and sensitivity to bright light, sound and temperature extremes. MCS sufferers also become allergic to foods and common inhalant allergens as well as artificial flavors, colors, and preservatives.

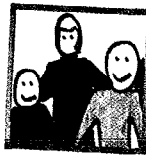
MCS is a permanent condition. Severely affected people have lost their jobs and friends. Their symptoms leave them incapacitated and essentially home bound. Sufferers often create a home "sanctuary" relatively free from chemical emissions, where they spend as much time as possible. Doctors can only recommend avoiding the offending products since there are no medications or treatments. As a result, they experience intense isolation, loss of self-esteem and depression.

Dr. Iris Bell, a leading MCS researcher and chief of geriatric psychiatry at Tucson Veterans Affairs Hospital in Arizona, estimates that as many as 16 million people in the U.S. now have hypersensitive reactions to chemicals.

NEWEST ESTIMATE- 50 MILLION WORLD WIDE  
20 MILLION USA

Dockets Management Branch  
The Food & Drug Administration  
Dept. of Health & Human Services  
RM. 1-23  
12420 Parklawn Dr.  
Rockville, MD. 20857  
Docket # 99 P1340/CP





Ms Alice Farber  
32 Alpine Way  
Huntingtn Sta NY 11746-4602